MEDICAID DRUG REBATE PROGRAM Release No. 14

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All Participating Drug Manufacturers

STAGES OF THE DISPUTE RESOLUTION PROCESS

Stages of the Dispute Resolution Process (Attachment A), has been designed to provide general guidelines and time-limits associated with the dispute resolution process. We still stress the importance of open communication between both parties and keeping the Regional Office Drug Payment Coordinators involved.

EFFECT OF ADMINISTRATIVE FEES ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE

Recently, we have received numerous inquiries from various manufacturers or their representatives requesting guidance on whether administrative fees paid to buyers of covered outpatient drugs have any effect on AMP and/or best price calculations. We consider administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, to be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP, and best price.

Except for the explicitly listed exclusions in the rebate agreement and in section 1927 of the Social Security Act, and, in accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data "... must be adjusted by the Manufacturer if ... other arrangements subsequently adjust the prices actually realized." Thus, we consider any price adjustment which ultimately affects the price actually realized by the manufacturer as "other arrangements" and, as required by the

rebate agreement, included in the calculations of AMP and best price.

Please remember that any prices which are nominal in amount, that is, less than 10% of the AMP in the same quarter for which the AMP is computed, are excluded from the best price calculation. Therefore, if any arrangement results in prices which are nominal, those sales and prices do not affect best price and must be excluded by the manufacturer.

NOTICE TO HCFA OF REVISED AVERAGE MANUFACTURER PRICE (AMP) CALCULATION METHODOLOGY

Several drug labelers have notified HCFA of their intent to recalculate the AMPs for selected drug products. In those situations where you plan to submit revised AMPs and are changing the method by which you calculate the AMPs, contact HCFA prior to submitting revised AMPs to explain why you are recalculating the AMPs, the magnitude of the changes, the rationale being used, documentation to support the changes and whether these changes will affect your AMPs both retroactively and prospectively. HCFA will review this documentation and decide whether the proposed change conforms to the statute and the manufacturer's agreement. Do not submit any recalculated AMPs until notified to do so by HCFA. All documentation should be submitted to:

Medicaid Drug Rebate Program
P.O. Box 26686
Baltimore, MD 21207-0486

UNIQUE MEDICAID FACTORS TO BE CONSIDERED BY DRUG LABELERS IN REBATE DISPUTES

From the beginning of this program, HCFA has called upon the expertise of State Medicaid officials in trying to solve problems that occur periodically. This group of State officials referred to as the Pharmacy Technical Advisory Group (P-TAG) have provided information and help on numerous occasions. Recently, the members of the P-TAG developed a list of factors unique to State Medicaid drug programs that may help to reduce the number of rebate disputes by promoting a better understanding by the drug companies.

These factors include:

oMedicaid data includes nursing home dispensing data. Possibly, that information may not be included in manufacturer marketing data;

oRegional marketing data of manufacturers may fail to take into account any border pharmacies, chain drug store distribution systems or regional and national buying groups;

oPrescription limits (e.g., 3 per month) can result in large quantities dispensed per prescription, legitimately;

oIngredients of compounded prescriptions billed by NDC may be claimed for rebates;

oThe total amount reimbursed for prescriptions is not a reliable indicator of units dispensed since copayments, third party liability and sale pricing (loss leaders) can all reduce the total amount reimbursed;

oTopical prescriptions do not always represent one tube per prescription;

oState front end claim edits for maximum quantities must be known by manufacturers since without them, unusual quantities may appear on claims;

oDrugs the manufacturer may not consider outpatient drugs may be claimed for rebate when separate drug claims were generated and paid by the States (e.g. injectables);

oOutside data sources may not be infallible as to accuracy;

oSales data may fail to reflect all sales to wholesalers or individual manufacturer's return/substitution policies may not be reflected in sales data but do affect actual inventory at the pharmacy;

oConflicts regarding billing units still exist between the States, HCFA, First DataBank and MediSpan. This has caused a certain amount of under/over reporting by States;

oManufacturers need to explain why an NDC is not valid (e.g. expired product);

oManufacturers should know the States' unit dose policies and how they might impact rebate claims;

oMedicaid population as a percent of total State population is not a reliable indicator of Medicaid drug utilization;

oAll States have a period of time, sometimes up to a year, from the date of service of a claim in which it can be submitted for payment; (e.g. Manufacturer sales in a quarter may not

be indicative of Medicaid claims paid in a quarter); **and**

oThe rebate invoices you receive from States are reflective of the claims **paid** during that calendar quarter **not** the number of claims dispensed to Medicaid patients.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from January 3, 1994 through December 19, 1994. These rates are to be used to calculate interest owed States on overdue rebates.

TOPIC INDEX

For your convenience, also attached is a topic index of all items covered in prior releases.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

Sally K. Richardson
Director
Medicaid Bureau

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators Division of Medicaid